

EXHIBIT I

Docket No.: 0425-1218PUS1  
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Tetsuya OKANO et al.

Application No.: 10/551,654

Confirmation No.: 5662

Filed: July 10, 2006

Art Unit: 1616

For: A COMPOSITION FOR PRODUCTION OF A  
STERILIZER AND A PROCESS FOR  
PRODUCING ORGANIC PERACID

Examiner: A. L. Fisher

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Noboru Matsuo, hereby declare as follows:

I am one of the co-inventors of the invention as described and claimed in the above-identified patent application.

I have carried out additional examples myself or under my direct supervision. Test procedures and results are shown below.

Side-by-Side Comparison between the Present Invention and the Primary Reference

The Examiner has cited U.S. Patent No. 5,827,447 to Tamura et al. (hereinafter, "Tamura '447'") as the primary reference in a rejection under 35 U.S.C. § 103(a). I consider Example 11 of Tamura '447 to be the closest example to the present invention.

Enclosed herewith is Table A, which shows inventive Example 3-3 and Tests 1 and 2 as comparative examples. Test 1 was carried out using the same materials and methods as disclosed for Example 11 of Tamura '447. Test 2 was carried out using the same materials and methods as disclosed for Example 11 of Tamura '447, except triacetone was used in place of NOBS.

The obtained products were evaluated in the same way as Example 3-3 of the present specification. The results of all three examples are shown in Table A.

As shown in Table A, the number of remaining microorganisms with the inventive example is much less than the number with the comparative examples. As such, the present invention provides unexpectedly superior results.

**Side-by-Side Comparison between the Present Invention and the Secondary Reference**

The Examiner has cited U.S. Patent No. 5,869,440 to Kobayashi et al. (hereinafter, "Kobayashi '440") as the secondary reference in a rejection under 35 U.S.C. § 103(a). I consider Comparative Example 4 of Kobayashi '440 to be relative to the present invention.

Enclosed herewith is Table B, which shows inventive Example 3-3 and continued Example 3-3 with changed reaction temperatures and reaction times and Test 3 and continued Test 3 with changed storage temperatures and storage terms as comparative examples.

Test 3 was carried out using the same materials and methods as disclosed for Comparative Example 4 of Kobayashi '440, except changed storage temperatures and storage terms.

The obtained products were evaluated in the same way as Example 3-3 of the present specification. The results are shown in Table B.

As shown in Table B, the number of remaining microorganisms with the inventive example is much less than the number with the comparative examples. As such, the present invention provides unexpectedly superior results.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S. Code 1001 and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

By: Noboru Matsuo  
Noboru Matsuo

Date: August 29, 2010

Table A

components	used materials	Example 3-3 of USSN 10/551654	Test 1 Example 11 of Tamura et al.	Test 2
Betaian surfactant*			10.0	10.0
(A)	Triacetin	5.0	-	2.0
	NOBS	-	2.0	-
(B)	H2O2	1.5	5.0	5.0
Organic phosphoric acid (Purity)	HEDP** EDTMP***	0.1 -	- 0.1	- 0.1
Alkaline pH adjusting agent	NaOH	2.0	-	-
Acidic pH adjusting agent	Phosphoric acid(65%) Sulfuric acid	5.0 -	- very small amount	- very small amount
Total		110.0	100.0	100.0
(A)/(B) molar ratio		0.52	0.04	0.08
Organic peracid concentration(ppm) after preparation		27000	500	500
pH of aqueous solution for sterilization (25°C)		3.7	2.0	2.0
Number of remaining microorganisms	Bacillus cereus IFO13494 Bacillus subtilis var. niger	<50 <50	1.8 x 10 <sup>7</sup> 2.6 x 10 <sup>7</sup>	1.5 x 10 <sup>7</sup> 2.4 x 10 <sup>7</sup>

Note: \* is softazoline LSE. \*\* is Dequest 2010. \*\*\* is Dequest 2046  
 "1.5" as the amount of H2O2 of Example 3-3 is equivalent to "4.3  
 g" of Table 10 of the instant application. "4.3 g" of Table 10 is the  
 amount of the 35 wt.% aqueous solution of H2O2. 4.3 g x 0.35% is  
 equal to 1.5.

Table B

components		USN 10/551654						Kobayashi et al.					
		Example 3-3								Test 3, Comparative Example 4			
(A)	Triaethin	5.0							2.00 **				
(B)	H2O2	1.5							2.75 **				
Organic phosphoric acid HEDP*		0.1											
Alkali pH NaOH adjusting agent sodium ortho-silicate		2.0											
Acid pH adjusting agent 85% phosphoric acid		5.0							1.5 **				
Total		11.0							100.00				
(A)/(B) molar ratio at the first step		0.52							0.11				
<u>Reaction temperature</u>		25°C~33°C		←	←	←	←	←	←	←	←		
<u>Reaction time</u>		10 minutes	minutes	1 day	5 days	5 days							
<u>Storage of each solution Temperature</u>													
<u>Condition of Kobayashi</u>													
term													
Concentration of peracid after preparation (ppm)		27000	11000	1500	150	=0			Just after 120 minutes	1 day	5 days		
pH of aqueous solution for sterilization(25°C)		3.7	3.7	3.1	3.0	3.0			13000	=0	=0		
Number of remaining Bacillus F013494 (CFU/mL)		<50	<50	-	9.8x10 <sup>6</sup>	1.0x10 <sup>7</sup>			10.5	9.5	9.1		
Bacillus var.niger		<50	<50	-	2.9x10 <sup>7</sup>	3.3x10 <sup>7</sup>			1.5x10 <sup>7</sup>	8.4x10 <sup>6</sup>	-		
									1.2x10 <sup>7</sup>	8.9	8.9		
									4.0x10 <sup>7</sup>	3.1x10 <sup>7</sup>	-		
									3.8x10 <sup>7</sup>	2.6x10 <sup>7</sup>	-		
sterilizing test with a diluted aqueous solution having an organic peracid's concentration of 3000 ppm		sterilizing test with a starting aqueous solution.		sterilizing test with a starting aqueous solution.		sterilizing test with a starting aqueous solution.		sterilizing test with a starting aqueous solution.		sterilizing test with a starting aqueous solution.			

\*: is Daquest 2010

\*\* the amounts of (A) (B) and Alkali pH adjusting agent are recited for 100 parts by weight of the total of (A) and (B).

← means the same as the left-sided term

EXHIBIT II

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Sir:

I, Noboru Matsuo, hereby declare as follows:

I am one of the co-inventors of the invention as described and claimed in the above-identified patent application.

I have carried out additional examples myself or under my direct supervision. Test procedures and results are shown below.

Example 5-9-a and Example 5-10-a

Example 5-9 and Example 5-10 were experimentally followed. Test conditions and test results are described in Table C, including additional conditions, hereto attached. An alkali agent and an acid agent were the alkaline pH adjusting agent and the acidic pH adjusting agent used in Example 1 of the instant application. The glycerin fatty acid ester had a fatty acid group having 8

carbon atoms and was the same as used in Example 1 of the instant application..

It is noted that Example 5-9-a is superior to Example 5-10-a by about 18 % in view of the reaction efficiency of production of the organic peracid.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S. Code 1001 and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

By: Noboru Matsuo

Noboru Matsuo

Date: August 29, 2010

Attachment: Table C

Table C

		Ex-9-a		Ex-10-a	
(A)	glycerin fatty acid ester	5 (g)	0.0229 (mol)	8 (g)	0.0367 (mol)
(B)	H <sub>2</sub> O <sub>2</sub>	0.29 (g)	0.0030 (mol)	0.29 (g)	0.0030 (mol)
(C)	water	55 (g)		60 (g)	
Alkali agent (initiator) + acid agent (terminating agent)					
Total		10 (g)		10 (g)	
		70.29 (g)		78.29 (g)	
peracid (C <sub>7</sub> H <sub>15</sub> GOOOH: MW=160)					
	concentration	4500 (ppm)	0.00198 (mol)	5500 (ppm)	0.00269 (mol)
	amount	0.3163 (g)		0.4306 (g)	
efficiency of reaction	peracid/(A)	0.0863		0.0733	



## EXHIBIT III

Table 1

Compounding component	Products of the invention									
	1-1	1-2	1-3	1-4	1-5	1-6	1-7	1-8	1-9	1-10
Ethylene glycol monoacetate	2g (0.0192)							3g (0.0298)		
Ethylene glycol diacetate		2g (0.0137)							3g (0.0205)	
Diacetin			2g (0.0114)							3g (0.0170)
(A) Triacetin				2g (0.0092)						
Pentaerythritol tetraacetate					2g (0.0066)					
Pentaerythritol-β-D-glucose						2g (0.0051)				
Glycerine fatty acid ester							2g (0.0092)			
Aqueous hydrogen peroxide (35 wt%)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)
(B) Sodium percarbonate										
Sodium perborate										
(A)/(B) molar ratio	0.65	0.47	0.39	0.31	0.22	0.17	0.31	0.98	0.70	0.58
pH(25°C)	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.9	4.9	4.9
Organic peracid concentration (ppm)	6900	17000	10000	22900	4500	25800	2700	9800	21500	16100
Just after pH adjustment										
30 minutes after pH adjustment	6800	17000	9600	20300	4500	24100	2700	9600	21000	15700
60 minutes after pH adjustment	6800	16800	9100	18600	4300	22900	2500	9300	19800	14200
120 minutes after pH adjustment	6200	15200	8200	17500	3900	19800	2000	9000	18400	12300
Degree of remaining organic peracid (%)	89.9	89.4	82.0	76.4	86.7	76.7	74.1	91.8	85.6	76.4
H <sub>2</sub> O <sub>2</sub> /ester group molar ratio	1.53	1.07	1.28	1.07	1.11	1.15	3.20	1.02	0.717	0.865

Table 2

		Product of the invention									
		1-11	1-12	1-13	1-14	1-15	1-16	1-17	1-18	1-19	1-20
Compounding components	Ethylene glycol monoacetate					5g (0.0481)					
	Ethylene glycol diacetate						5g (0.0342)				
	Diacetone							5g (0.0284)			
	(A) Triacetone	3g (0.0138)							5g (0.0229)		
	Pentaerythritol tetraacetate		3g (0.0099)							5g (0.0164)	
	Pentaerythritol-β-D-glucose			3g (0.0077)							5g (0.0128)
	Glycerine fatty acid ester				3g (0.0138)						
	Aqueous hydrogen peroxide (35 wt%)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)
	(B) Sodium percarbonate										
	Sodium perborate										
(A)/(B) molar ratio		0.47	0.34	0.26	0.47	1.64	1.16	0.97	0.78	0.56	0.44
pH(25°C)		4.9	4.9	4.9	4.9	3.8	3.8	3.8	3.8	3.8	3.8
Organic peracid concentration (ppm)	Just after pH adjustment	25400	8600	28700	4100	12300	22000	23200	31700	9300	33500
	30 minutes after pH adjustment	24300	6100	27400	3800	11700	20500	22200	29900	8600	32000
	60 minutes after pH adjustment	23600	5700	26800	3700	10500	18800	21000	27600	7800	30600
	120 minutes after pH adjustment	20500	5000	24900	3500	10000	17800	20300	25800	7200	28100
Degree of remaining organic peracid (%)		80.7	73.5	86.8	85.4	81.3	80.9	87.5	81.4	77.4	83.9
H <sub>2</sub> O <sub>2</sub> /ester group molar ratio		0.710	0.742	0.764	2.13	0.611	0.430	0.518	0.428	0.448	0.459

Table 3

		Product of the invention											
		1-21	1-22	1-23	1-24	1-25	1-26	1-27	1-28	1-29	1-30		
Compounding components	Ethylene glycol monoacetate	2g (0.0192)											
	Ethylene glycol diacetate		2g (0.0137)						3g (0.0205)				
	Diacetin			2g (0.0114)						3g (0.0138)			
	(A) Triacetin				2g (0.0092)								
	Pentaerythritol tetraacetate					2g (0.0056)							
	Pentaerythritol-β-D-glucose						2g (0.0051)					3g (0.0077)	
	Glycerine fatty acid ester							2g (0.0092)					
	Aqueous hydrogen peroxide (35 wt%)												
	(B) Sodium hydrogen percarbonate	4.55g (0.0294)	4.55g (0.0294)	4.55g (0.0294)	4.55g (0.0294)	4.55g (0.0294)	4.55g (0.0294)	4.55g (0.0294)					
	Sodium perborate								5.00g (0.0294)	5.00g (0.0294)	5.00g (0.0294)		
(A)/(B) molar ratio		0.65	0.47	0.39	0.31	0.22	0.17	0.31	0.70	0.47	0.26		
pH(25°C)		4.2	4.2	4.2	4.2	4.2	4.2	4.2	4.2	4.5	4.5		
Organic peracid concentration (ppm)	Just after pH adjustment	7000	17500	11500	23100	4800	26200	2900	23000	23600	26700		
	30 minutes after pH adjustment	6900	17000	9600	21500	4400	25100	2800	21600	21500	24300		
	60 minutes after pH adjustment	6800	16200	9300	19800	4300	22500	2600	20100	19700	23900		
	120 minutes after pH adjustment	6200	15000	8500	18600	3800	20000	2200	19200	18300	21300		
Degree of remaining organic peracid (%)		88.6	85.7	73.9	80.5	82.6	76.3	75.9	83.5	77.5	79.8		
H <sub>2</sub> O <sub>2</sub> /ester group molar ratio		1.53	1.07	1.28	1.07	1.11	1.15	3.20	0.717	0.710	0.764		

Table 6

Compounding ingredients	Product of the invention									
	2-1	2-2	2-3	2-4	2-5	2-6	2-7	2-8	2-9	2-10
Ethylene glycol monoacetate	2g (0.0192)							3g (0.0288)		
Ethylene glycol diacetate		2g (0.0137)								
Diacetin			2g (0.0114)						5g (0.0229)	
(A) Triacetin				2g (0.0092)						
Pentaerythritol tetraacetate					5g (0.0164)					
Pentaacetyl-β-D-glucose						2g (0.0051)	5g (0.0229)			5g (0.0128)
Glycerine fatty acid ester										
Aqueous hydrogen peracid (35 wt%)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)
(B) Sodium percarbonate										
Sodium perborate										
(A)/(B) molar ratio	0.65	0.47	0.39	0.31	0.56	0.17	0.78	0.98	0.78	0.44
pH(25°C)	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.9	3.8	3.8
Organic peracid concentration (ppm)	5000	5000	4000	4000	4000	4000	4000	4000	4000	4000
Number of remaining microorganisms (CFU/mL)	<50	<50	<50	<50	<50	<50	150	<50	<50	<50
<i>Bacillus subtilis</i>										
<i>Bacillus circulans</i>							200	<50	<50	<50
<i>Aspergillus niger</i>							150	<50	<50	<50
H <sub>2</sub> O <sub>2</sub> /ester group molar ratio	1.53	1.07	1.28	1.085	0.448	1.15	1.28	1.02	0.428	0.459

Table 7

		Product of the invention									
		2-11	2-12	2-13	2-14	2-15	2-16	2-17	2-18	2-19	2-20
Compounding ingredients	Ethylene glycol monoacetate	2g (0.0192)							3g (0.0288)		
	Ethylene glycol diacetate		2g (0.0137)								
	Diacetin			2g (0.0114)						5g (0.0229)	
	(A) Triacetin				2g (0.0092)						
	Pentaerythritol tetraacetate					5g (0.0164)					
	Pentaacetyl - $\beta$ -D-glucose						2g (0.0051)				5g (0.0128)
	Glycerine fatty acid ester							5g (0.0229)			
	Aqueous hydrogen peroxide (35 wt%)										
	(B) Sodium percarbonate	4.55g (0.0294)	4.55g (0.0294)	4.55g (0.0294)	4.55g (0.0294)	4.55g (0.0294)	4.55g (0.0294)	4.55g (0.0294)			
	Sodium perborate								5.00g (0.0294)	5.00g (0.0294)	5.00g (0.0294)
(A)/(B) molar ratio		0.65	0.47	0.39	0.31	0.56	0.17	0.78	0.98	0.78	0.44
pH(25°C)		4.2	4.2	4.2	4.2	3.9	4.2	3.9	4.5	3.9	3.9
Organic peracid concentration (ppm)		4000	4000	4000	4000	4000	4000	4000	4000	4000	4000
Number of remaining microorganisms (CFU/mL)	<i>Bacillus subtilis</i>	<50	<50	<50	<50	<50	<50	200	<50	<50	<50
	<i>Bacillus circulans</i>	<50	<50	<50	<50	<50	<50	200	<50	<50	<50
	<i>Aspergillus niger</i>	<50	<50	<50	<50	<50	<50	250	<50	<50	<50
	percarbonate/ester group molar ratio	1.53	1.07	1.28	1.095	0.448	1.15	1.28	1.02	0.428	0.459



Table 12

Manufacturing condition			Example											
			5-1	5-2	5-3	5-4	5-5	5-6	5-7	5-8	5-9	5-10		
Charging amounts	(A)	Ethylene glycol diacetate	2g (0.0137)	3g (0.0205)	5g (0.0342)									
		Triacetin				2g (0.0092)	3g (0.0138)	5g (0.0229)						
	(B)	Pentaacetyl-β-D-glucose								2g (0.0051)	3g (0.0077)	5g (0.0229)	8g (0.0367)	
		Glycerin fatty acid ester												
		Aqueous hydrogen peroxide (35 wt%)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	2.86g (0.0294)	0.29g (0.0030)	0.29g (0.0030)	
		Sodium percarbonate												
	(C)	Sodium perborate												
		water	48g	48g	55g	48g	48g	55g	48g	55g	55g	60g		
	(A)/(B) molar ratio		0.47	0.70	1.16	0.31	0.47	0.78	0.17	0.26	7.63	12.23		
		[(A)+(B)]/(C) ratio by weight	0.063	0.083	0.109	0.063	0.083	0.109	0.063	0.073	0.093	0.135		
	pH in second step (25°C)		3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7		
		Organic peracid concentration (ppm)		18300	22100	23600	22300	26100	33700	28900	29900	4500	5500	
		just after second step		17500	21300	21600	21000	25100	30200	25800	27900	4200	5100	
		30 minutes after second step		16300	19800	20500	19300	24300	28700	24600	25800	4000	4800	
		60 minutes after second step												
		Degree of remaining organic peracid (%)		89.1	89.6	86.9	86.5	93.1	85.2	91.4	86.3	88.9	87.3	
		Degree of remaining hydrogen peroxide (%)		48.3	41.8	39.9	41.2	28.7	8.1	38.2	25.3	28.7	19.9	
H <sub>2</sub> O <sub>2</sub> /ester group molar ratio				1.07	0.717	0.430	1.07	0.710	0.428	1.15	0.764	0.131	0.082	





Table 14

										Example										
										5-21	5-22	5-23	5-24	5-25	5-26	5-27	5-28	5-29	5-30	
Manufacturing conditions	(A)	Ethylene glycol diacetate		2g (0.0137)	3g (0.0205)	5g (0.0342)														
		Triacetin					2g (0.0092)	3g (0.0138)	5g (0.0229)											
		Pentaacetyl- $\beta$ -D-glucose												2g (0.0051)	3g (0.0077)					
		Glycerin fatty acid ester														5g (0.0228)	8g (0.0367)			
	(B)	Aqueous hydrogen peroxide (35 wt%)																		
		Sodium percarbonate	4.55g (0.0294)	4.55g (0.0294)	4.55g (0.0294)	4.55g (0.0294)	4.55g (0.0294)													
		Sodium perborate														5.00g (0.0294)	5.00g (0.0284)	0.5g (0.0029)	0.5g (0.0029)	
	(C)	Water	55g	55g	55g	55g	55g											55g	55g	55g
		(A)/(B) molar ratio	0.47	0.70	1.16	0.31	0.47	0.78	0.17	0.26	7.90	12.66								
		[(A)+(B)]/(C) weight ratio	0.055	0.073	0.109	0.055	0.073	0.109	0.055	0.073	0.093	0.147								
pH in second step(25°C)		4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5									
Organic peracid concentration (ppm)		18500	22000	23000	22100	27300	33500	28400	30100	4500	5300									
	Degree of remaining organic peracid (%)	Just after second step	17200	21000	22300	21600	25400	30800	24100	28300	4300	5300								
		30 minutes after second step	15800	19900	21900	20900	23200	28600	22500	25100	4100	5000								
		60 minutes after second step	85.4	90.5	93.5	94.6	85.0	88.4	85.2	83.4	91.1	94.3								
	Degree of remaining hydrogen peracid (%)	46.2	38.6	35.6	37.2	20.8	6.9	30.9	21.1	25.9	17.4									
H <sub>2</sub> O <sub>2</sub> /ester group molar ratio		1.07	0.717	0.430	1.07	0.710	0.428	1.15	0.764	0.127	0.079									

Table 23

[illegible]